

REMARKS

I. Status of the Claims

Claims 1-7 and 23-37 are currently pending, with claims 1-7, 27-30 and 35-37 withdrawn from consideration as drawn to a non-elected invention. Thus, claims 23-26 and 31-34 are currently under examination.

Upon entry of this amendment, claims 23-26 and 31 are amended without prejudice or disclaimer and new claims 38-50 are introduced. The amended and new claims find support throughout the specification including, for example, the following sections:

|                       |  |
|-----------------------|--|
| Claims 23, 24 and 38: | Page 53, line 25 to page 65, line 13; and page 79, line 10                     |
| Claim 31:             | Original claims 1 and 31; and page 69, line 20 to page 72, line 28.            |
| Claims 39 and 43-50:  | Page 53, line 25 to page 65, line 13.  |
| Claim 40              | Page 58, line 27 to page 59, line 32; and page 62, line 11 to page 63, line 4. |
| Claims 41 and 42:     | Page 63, lines 11-27   |

II. Objections to Specification

The hyperlink that was objected to has been removed.

III. Claim Rejections under 35 U.S.C. 112, Second Paragraph

Claims 23-26 and 31-34 are rejected as being indefinite because of use of singular and plural forms of certain elements. These claims have been amended to clarify usage.

Claims 25 and 26 are rejected because the terms "PDZ" and "PL" are said to be unclear. These claims have been amended for consistency with usage in the base claim.

Claims 31-34 are rejected for use of the term "detering." These claims have been amended to correct this typographical error so the claims now recited to "determining."

Claims 31-34 are also rejected because of inconsistencies in language between the resolution step and the preamble. Claim 31 has been amended to be in independent form and the preamble amended for consistency with the resolution step.

Finally, claims 31-34 are rejected because they allegedly omit essential steps, specifically the steps needed to determine the apparent affinity of binding between a PDZ-containing polypeptide and a PL protein. For the reasons that follow, applicants respectfully disagree.

As an initial matter, it is noted that the MPEP section cited by the Examiner (section 2172.01) indicates that a claim which omits matter disclosed to be essential should be rejected under 35 U.S.C. §112, first paragraph; whereas, a claim that fails to interrelate elements disclosed to be essential should be rejected under 35 U.S.C. §112, second paragraph. Because the claims stand rejected for omitting an essential element, it seems that the proper statutory basis for the rejection should be 35 U.S.C. §112, first paragraph rather than 35 U.S.C. §112, second paragraph. If this ground for rejection is maintained, clarification of the statutory basis for the rejection is requested.

The patent laws are clear that “essential matter” or “essential elements” are only those matters or elements disclosed to be essential to the invention as described in the specification or in other statements of record. (MPEP 2164.08(c) and 2172.01). MPEP 2164.08(c) states that “an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended.” This section of the MPEP also states that features that are merely preferred are not to be considered critical.

The Office Action contends that the steps to determine apparent binding affinity must be included because they are essential steps. In view of the foregoing definition of “essential” elements, the steps for determine binding affinity need not be described unless the specification states that the particular steps for calculating binding affinity are critical to the invention. This is not the case. To the contrary, the specification notes that the “binding affinity itself can be determined using any suitable equation [citations omitted] or software” (page 72, lines 12-15).

So the specification does not teach that the steps for determining the apparent affinity of binding are critical; rather it teaches that a number of methods can be used. As such, details of the determination process are not required.

The claims provide the requisite level of detail in specifying that the method involves determining the amount of binding of a PL protein to a PDZ-containing polypeptide at several PL concentration and that these values are then used to calculate the binding affinity. As the specification notes, various equations can be used to calculate binding affinity from these values. While not deemed necessary, independent claim 31 has been amended to clarify that the apparent binding affinity between the PDZ-containing polypeptide and the PL protein is determined from the amount of binding at the different PL concentrations. This amendment is not a narrowing amendment because it simply makes explicit what was previously implicit. The amended claim is thus entitled to the same range of equivalents as the original claim.

#### IV. Rejection of Claims under 35 U.S.C. 102

Claims 23, 24 and 26 are rejected as anticipated under 35 U.S.C. 102(b) as anticipated by a scientific article written by Gee et al. (J. Neurosci. 18:128-137 (1988)) (hereinafter "Gee").

In response, it is noted that independent claim 23 has been amended so the method involves contacting at least one PL protein with an array of at least 5 PDZ-containing polypeptides of different amino acid sequence and then detecting binding of the PL protein to one or more of the PDZ-containing polypeptides. Gee does not teach or suggest a method using such an array. As such, Gee fails to anticipate claim 23. For at least the same reasons, Gee also fails to anticipate those claims that depend upon claim 23 (i.e., claims 25, 26 and 38-42).

Claim 31 has been rewritten into independent form. This claim was not rejected as anticipated by Gee. So claim 31 and its dependent claims (i.e., claims 31-34) are deemed patentable over Gee.

New claim 43 describes another method for identifying an interaction between a PDZ domain and a PL protein. In this particular method, a PL fusion protein is contacted with a PDZ fusion protein under conditions in which they react to form a complex. The PL fusion protein

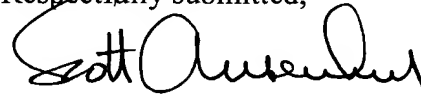
comprises a PL sequence and a first epitope tag and the PDZ fusion protein comprises a PDZ domain and a second epitope tag. Complex is detected by reacting it with a labeled antibody that recognizes the PL fusion protein or an antibody thereto.

Related claim 47 describes a method in which a PDZ fusion protein is contacted with an immobilized PL fusion protein under conditions in which they react to form a complex. Here, too, the PL fusion protein comprises a PL sequence and a first epitope tag and the PDZ fusion protein comprises a PDZ domain and a second epitope tag. Complex is detected by reacting it with a labeled antibody that recognizes the PDZ fusion protein or an antibody thereto.

Neither of the method recited in claims 43 or 47 are taught or suggested by Gee. Thus, these claims and their dependents are not anticipated by Gee.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,



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